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Statement of the American Dental Association Before
The Connecticut Legislative Joint Committee on Public Health Products
HB 5243
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The American Dental Association (ADA) is the world's largest and oldest dental association, representing more than 155,000 dentists nationwide. For over 150 years, the ADA has actively sought to promote the oral health of the public and promote the development of scientifically accurate information.

The ADA Supports current FDA Policy on Dental Amalgam

The ADA is pleased to have worked with the appropriate regulatory agencies in the past and will continue to do so in the future.

In the US, it is the US Food and Drug Administration (FDA) that is charged with the regulation of dental amalgam. That Agency has been reviewing dental amalgam for many years that has involved review of hundreds of scientific studies relating to the safety of dental amalgam. After all those years of study and analysis, the FDA has concluded:[1]

- "Dental amalgam has been demonstrated to be an effective restorative material that has benefits in terms of strength, marginal integrity, suitability for large occlusal surfaces, and durability."
- **"Clinical studies have not established a causal link between dental amalgam and adverse health effects in adults and children age six and older."**
- "In addition, two clinical trials in children aged six and older did not find neurological or renal injury associated with amalgam use."
- "FDA has found that scientific studies using the most reliable methods have shown that dental amalgam exposes adults to amounts of elemental mercury vapor below or approximately equivalent to the protective levels of exposure identified by ATSDR and EPA. Based on these findings and the clinical data, **FDA has concluded that exposures to mercury vapor from dental amalgam do not put individuals age six and older at risk for mercury-associated adverse health effects."**
- "FDA estimates that the estimated daily dose of mercury in *children under age six* with dental amalgams is lower than the estimated daily adult dose. **The exposures to children [under six] would therefore be lower than the protective levels of exposure identified by ATSDR and EPA."**
- "In addition, the estimated concentration of mercury in breast milk attributable to dental amalgam is an order of magnitude below the EPA protective reference dose for oral exposure to inorganic mercury. **FDA has concluded that the existing data support a finding that infants are not at risk for adverse health effects from the breast milk of women exposed to mercury vapors from dental amalgam."**

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[1] Food and Drug Administration, HHS. Dental devices: classification of dental amalgam, reclassification of dental mercury, designation of special controls for dental amalgam, mercury, and amalgam alloy. Final rule. 74 Fed Reg. 38685-714, 38693-4 (emphasis added).

- The state of the science on the safety of dental amalgam is clear. The best evidence continues to support the safety of dental amalgam. This evidence simply does not support a link between dental amalgam and systemic diseases or risks to pregnant women or developing fetuses. Nor does the evidence support the existence of "sensitive populations" at risk from dental amalgam.[2] While scientific data supports the safety and efficacy of dental amalgam, the ADA supports the FDA's decision to continue a rigorous and comprehensive review of the issue, as supported by the scientific method. And the message from the ADA is clear: If substantial scientific evidence showed dental amalgam posed a threat to the health of dental patients or any segment of that population, the ADA would advise dentists to stop using it.

The Benefits of Dental Amalgam and the Costs of Any Restriction on the Availability of Dental Amalgam

While the scientific evidence regarding the safety of dental amalgam is well established, those considering the issue must do more than focus on the "risk" side of the equation. To look at it another way, restrictive regulation of dental amalgam would itself have very substantial health and safety, as well as monetary, costs associated with it.

Were the use of amalgam prevented, the ADA is concerned it would hurt efforts to address the oral health needs of both individuals and the entire population. Individually, it would deprive some patients of the freedom to choose the optimal treatment for them. In others, especially young children and those with special needs, where it may not be possible to create the dry environment required for placement of alternative restorative materials, the elimination of amalgam as a treatment option could require the use of general anesthetics. This would create an increased risk from the use of such general anesthetics. The clinical indications for use also make amalgam one of the most important materials for underserved populations at high risk and with high disease rates. Restrictions on use would put a disparate burden on these populations from both a health and financial perspective.

Unwarranted action will also affect the entire population. As is discussed below, elimination of dental amalgam as an option will have a profound effect on the public health system because of the added cost of alternative treatments.

A 2007 peer-reviewed study examined the impact of partial and full bans on the use of dental amalgam. Among the conclusions were: [3]

- Without amalgam, the average price of restorations would go from $278 to $330 (an 18.7 percent increase);
- It is estimated that as the prices increased, there would be 15,444,021 fewer restorations each year;
- A ban on amalgam would increase the use of crowns and composite resins, both of which are more expensive;

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[2] The ADA does recognize, of course, that a very small segment of the population may experience localized allergic reactions to dental amalgam.

[3] Beazoglou T, Eklund S, Heffley D, Meiers J, Brown LJ, Bailit H, Economic Impact of Regulating the Use of Amalgam Restorations, Public Health Reports 2007 September-October; vol. 122, 657.

- Even limiting the ban to children would mean an increase of $1.1 billion the first year and $13 billion over a 15-year period.

Law and regulatory action must be supported by science. Clearly, any restriction on the use of dental amalgam will affect, adversely, the health of many individuals and the population as a whole. As prices rise, some will forego treatment. *Id.* Similarly, there is a monetary cost which is significant, both individually and in the aggregate. The monetary cost is significant because of its impact, deferred treatment and the loss of funds for other treatment and prevention. Indeed, the segment of the population at greatest risk from increases in cost of alternative treatments is that which can least afford it. Any rational risk assessment must account for this side of the equation: the costs of regulation.

There is a Lack of Sound Evidence That Amalgam Poses a Health Risk And Those Seeking to Ban It Misapply Scientific Principles

Some who support an outright ban of dental amalgam ignore or fail to understand the science supporting the conclusion that it remains a safe treatment option. Typically, they rely on non-peer-reviewed articles, studies that do not comply with Good Clinical Practice (GCP), or on studies which focus solely on sub-clinical effects at the cellular level, ignoring the dearth of evidence that amalgam causes humans any harm.

Finally, those seeking a ban or restriction on use rely on a false reading of the precautionary principle. Under this reading, unless the negative is proven (i.e. unless a study can "prove" that no one, anywhere, can ever be harmed), the use of amalgam must be ended. The problem with this approach to the precautionary principle is that it would result in the ban on almost every substance. For it is simply not possible to prove that anything is always safe. Even water cannot be "proven" safe because, at the wrong amount (dose) or ingested in the wrong way, harm is possible. While these amalgam opponents are, of course, free to advocate this or any other approach, the FDA is more constrained. As a British editor commented under similar circumstances: "But while it is one thing to debate an issue such as this..., it is quite another when a government or regulatory authority abruptly decides that it is time to ban amalgam on an emotional, or at the very least, un-critically appraised level."[4]

Conclusions

Dental amalgam remains a valuable restorative option for dentists and their patients. At present, there is no direct restorative material that works as well as amalgam for large fillings in the back teeth, in very deep fillings, or in fillings below the gum line. Alternatives are often less effective in these situations.

Amalgam is also an excellent restorative material for placement in a wet environment. This is critical when working with patients such as children or persons with developmental disabilities who might have difficulty sitting still in the dental chair. Without amalgam, dentists would be required to administer higher risk forms of anesthesia, to treat these patients with other restorative materials or by extraction.

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[4] **Editorial, Stephen Hancocks,** *British Dental Journal* **204**, 593 (2008) Published online: 14 June 2008 | doi:10.1038/sj.bdj.2008.492.

The ADA is a science-based organization and bases its comments solely on the scientific evidence. Based on that evidence, the ADA strongly urges the committee to support the well-researched and thoughtful conclusions reached of the FDA, after years of study.

We appreciate the opportunity to share these views with you and strongly urge the defeat of HB 5243.